

Amendments to the Claims

1. (currently amended) A method of treating allergy symptoms in a patient comprising administering a therapeutic amount of an antihistamine a drug condensation aerosol to the patient by inhalation,

wherein the drug is selected from the group consisting of azatadine, brompheniramine, carboxamine, chlorpheniramine, clemastine, cyproheptadine, loratadine, pyrilamine, hydroxyzine and promethazine, and

wherein the condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and having an MMAD of less than 3 μm and less than 5% antihistamine drug degradation products, to a patient by inhalation, upon activation by the patient of the formation of, and delivery of, the condensation aerosol 5 microns.

2. (currently amended) The method of according to claim 1, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns. said condensation aerosol is formed by

a. volatilizing an antihistamine drug under conditions effective to produce a heated vapor of the antihistamine drug; and

b. condensing the heated vapor of antihistamine drug to form condensation aerosol particles.

3. (currently amended) The method according to claim 2 1, wherein said administration results in a peak plasma drug concentration of said antihistamine drug is reached in less than 0.1 hours.

4. (cancelled)

5. (currently amended) The method according to claim 31, wherein the administered condensation aerosol is formed at a rate greater than 0.5 mg/second.

6. (original) The method according to claim 1, wherein at least 50% by weight of the condensation aerosol is amorphous in form.

7. (cancelled)

8. (cancelled)

9. (cancelled)

10. (cancelled)

11. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug azatadine condensation aerosol has an inhalable aerosol mass density of between 0.2 mg/L and 2.5 mg/L when delivered comprises between 0.2 mg and 2.5 mg of azatadine delivered in a single inspiration.

12. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug brompheniramine condensation aerosol has an inhalable aerosol mass density of between 0.8 mg/L and 10 mg/L when delivered comprises between 0.8 mg and 10 mg of brompheniramine delivered in a single inspiration.

13. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug carboxamine condensation aerosol has an inhalable aerosol mass density of between 0.8 mg/L and 10 mg/L when delivered comprises between 0.8 mg and 10 mg of carboxamine delivered in a single inspiration.

14. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug chlorpheniramine condensation aerosol has an inhalable aerosol mass density of between 0.5 mg/L and 5 mg/L when delivered comprises between 0.5 mg and 5 mg of chlorpheniramine delivered in a single inspiration.

15. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug clemastine condensation aerosol has an inhalable aerosol mass density of between 0.25 mg/L and 6 mg/L when delivered comprises between 0.25 mg and 6 mg of clemastine delivered in a single inspiration.

16. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug cyproheptadine condensation aerosol has an inhalable aerosol mass density of between 0.8 mg/L and 10 mg/L when delivered comprises between 0.8 mg and 10 mg of cyproheptadine delivered in a single inspiration.

17. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug loratadine condensation aerosol has an inhalable aerosol mass density of between 2 mg/L and 25 mg/L when delivered comprises between 2 mg and 25 mg of loratadine delivered in a single inspiration.

18. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug pyrilamine condensation aerosol has an inhalable aerosol mass density of between 6 mg/L and 70 mg/L when delivered comprises between 6 mg and 70 mg of pyrilamine delivered in a single inspiration.

19. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug hydroxyzine condensation aerosol has an inhalable aerosol mass density of between 2 mg/L and 100 mg/L when delivered comprises between 2 mg and 100 mg of hydroxyzine delivered in a single inspiration.

20. (currently amended) The method according to claim 7 1, wherein said the therapeutic amount of a drug promethazine condensation aerosol has an inhalable aerosol mass density of between 5 mg/L and 60 mg/L when delivered comprises between 5 mg and 60 mg of promethazine delivered in a single inspiration.

21. (currently amended) A method of administering an antihistamine drug to a patient to achieve a peak plasma drug concentration rapidly, comprising administering to the patient by inhalation an aerosol of an antihistamine drug having less than 5% antihistamine a drug condensation aerosol to a patient by inhalation,

wherein the drug is selected from the group consisting of azatadine, brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, loratadine, pyrilamine, hydroxyzine and promethazine, and

wherein the drug condensation aerosol is formed by heating a thin layer containing the drug, on a solid support, to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 3 microns 5 microns.

wherein the peak plasma concentration of the antihistamine drug is achieved in less than 0.1 hours.

22. (cancelled)

23. (currently amended) A kit for delivering a drug condensation aerosol comprising:

a) a thin coating of an antihistamine drug composition and layer containing the drug, on a solid support, wherein the drug is selected from the group consisting of azatadine, brompheniramine, carbinoxamine, chlorpheniramine, clemastine, cyproheptadine, loratadine, pyrilamine, hydroxyzine and promethazine, and

b) b. a device for dispensing said thin coating as a providing the condensation aerosol, wherein the condensation aerosol is formed by heating the thin layer to produce a vapor of the drug, and condensing the vapor to form a condensation aerosol characterized by less than 10% drug degradation products by weight, and an MMAD of less than 5 microns.

24. (cancelled)

25. (currently amended) The kit of according to claim 23, wherein the device for dispensing said coating of an antihistamine drug composition as an aerosol comprises:

(a) a flow through enclosure containing the solid support,

(b) contained within the enclosure, a metal substrate with a foil-like surface and having a thin coating of an antihistamine drug composition formed on the substrate surface,

(c) b. a power source that can be activated to heat the substrate to a temperature effective to volatilize the antihistamine drug composition contained in said coating, and solid support, and

(d) c. inlet and exit portals at least one portal through which air can be drawn through said device by inhalation,

wherein heating the substrate by activation of the power source is effective to form an antihistamine drug vapor containing less than 5% antihistamine drug degradation products, and drawing air through said chamber is effective to condense the antihistamine drug vapor to form aerosol particles wherein the aerosol has an MMAD of less than 3 microns produce a vapor of the drug, and drawing air through the enclosure is effective to condense the vapor to form the condensation aerosol.

26. (currently amended) The kit according to claim 25, wherein the heat for heating the substrate solid support is generated by an exothermic chemical reaction.

27. (currently amended) The kit according to claim 26, wherein said the exothermic chemical reaction is oxidation of combustible materials.

28. (currently amended) The kit according to claim 25, wherein the heat for heating the substrate solid support is generated by passage of current through an electrical resistance element.

29. (currently amended) The kit according to Claim 25, wherein said substrate the solid support has a surface area dimensioned to accommodate a therapeutic dose of an antihistamine drug composition in said coating the drug.

30. (currently amended) The kit according to claim 23, wherein a peak plasma drug concentration of antihistamine drug is obtained is reached in less than 0.1 hours after delivery of the condensation aerosol to the pulmonary system.

31. (currently amended) The kit of according to claim 23, further including instructions for use.

32. (new) The method according to claim 1, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.

33. (new) The method according to claim 2, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.

34. (new) The method according to claim 1, wherein the condensation aerosol comprises at least 80% drug by weight.

35. (new) The method according to claim 34, wherein the condensation aerosol comprises at least 95% drug by weight.

36. (new) The method according to claim 1, wherein the thin layer comprises at least 80% drug by weight.

37. (new) The method according to claim 36, wherein the thin layer comprises at least 95% drug by weight.

38. (new) The method according to claim 21, wherein the drug is azatadine.
39. (new) The method according to claim 21, wherein the drug is brompheniramine.
40. (new) The method according to claim 21, wherein the drug is carbinoxamine.
41. (new) The method according to claim 21, wherein the drug is chlorpheniramine.
42. (new) The method according to claim 21, wherein the drug is clemastine.
43. (new) The method according to claim 21, wherein the drug is cyproheptadine.
44. (new) The method according to claim 21, wherein the drug is loratadine.
45. (new) The method according to claim 21, wherein the drug is pyrilamine.
46. (new) The method according to claim 21, wherein the drug is hydroxyzine.
47. (new) The method according to claim 21, wherein the drug is promethazine.
48. (new) The kit according to claim 23, wherein the condensation aerosol is characterized by an MMAD of less than 3 microns.
49. (new) The kit according to claim 23, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 5 microns.
50. (new) The kit according to claim 48, wherein the condensation aerosol is characterized by an MMAD of 0.2 to 3 microns.
51. (new) The kit according to claim 23, wherein the condensation aerosol comprises at least 80% drug by weight.

52. (new) The kit according to claim 51, wherein the condensation aerosol comprises at least 95% drug by weight.

53. (new) The kit according to claim 23, wherein the thin layer comprises at least 80% drug by weight.

54. (new) The kit according to claim 53, wherein the thin layer comprises at least 95% drug by weight.

55. (new) The kit according to claim 23, wherein the drug is azatadine.

56. (new) The kit according to claim 23, wherein the drug is brompheniramine.

57. (new) The kit according to claim 23, wherein the drug is carbinoxamine.

58. (new) The kit according to claim 23, wherein the drug is chlorpheniramine.

59. (new) The kit according to claim 23, wherein the drug is clemastine.

60. (new) The kit according to claim 23, wherein the drug is cyproheptadine.

61. (new) The kit according to claim 23, wherein the drug is loratadine.

62. (new) The kit according to claim 23, wherein the drug is pyrilamine.

63. (new) The kit according to claim 23, wherein the drug is hydroxyzine.

64. (new) The kit according to claim 23, wherein the drug is promethazine.

65. (new) The kit according to claim 25, wherein the solid support has a surface to mass ratio of greater than 1 cm² per gram.

66. (new) The kit according to claim 25, wherein the solid support has a surface to volume ratio of greater than 100 per meter.

67. (new) The kit according to claim 25, wherein the solid support is a metal foil.

68. (new) The kit according to claim 67, wherein the metal foil has a thickness of less than 0.25 mm.